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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,119	03/11/2004	Yih-Lin Chung	55701-004002	8809

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OCCHIUTI ROHLICEK & TSAO, LLP
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CAMBRIDGE, MA 02138

EXAMINER

PAGONAKIS, ANNA

ART UNIT	PAPER NUMBER
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1628

NOTIFICATION DATE	DELIVERY MODE
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09/01/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/798,119	Applicant(s) CHUNG, YIH-LIN	
	Examiner ANNA PAGONAKIS	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,3,7-16 and 24-31 is/are pending in the application.
- 5a) Of the above claim(s) 7-10,12,13,24-28,30 and 31 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,3,11,14-16 and 29 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's amendment filed 6/16/2011 have been received and entered into the present application.

Applicant is reminded of the election of a proliferative disease, specifically, head and neck cancer made on 2/20/2007. As such, newly added claim 24 is withdrawn.

Applicant's arguments filed 6/16/2011 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Status of Claims

Claims 1, 3, 7-16 and 24-31 are pending.

Claims 3, 7-10, 12-13, 24-28 and 30-31 are withdrawn.

Claims 1, 11, 14-16 and 29 are currently under examination and the subject matter of the present Office Action.

Rejection necessitated by amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 24 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at

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the time the application was filed, has possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Newly amended claim 24 recites the limitation of "wherein the subject is cancer free." Applicant has stated in a footnote on page 6 of the response that "cancer-free" is supported by the specification as is evidenced by the specification in radiation experiments of Examples 3-8, 10 and 13 wherein the animal models used were cancer-free. This is not found persuasive. The invention as a whole contemplated the treatment of cancer, as is evidenced through the specification, specifically, page 1, lines 14-20; page 2, lines 27-29, page 9, lines 26-30; page 10, lines 10-12; page 15, lines 25-30.

While it is recognized that adequate written description of a limitation is not required to be stated *in haec verba* in the specification or claims as originally filed, adequate written support for all claim limitations must arise from either an explicit or an implicit suggestion by the disclosure to show that such a concept as now claimed was actually in possession of the Applicant at the time of the invention.

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir.

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1983))...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).”

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11, 14-16 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,877,213 [hereinafter referred to as “Samid”].

Samid et al. teach new approaches to the “treatment of human malignancies such as advanced prostatic cancer, melanoma, brain tumors, and others” (Col. 2, lines 35-38), including a method for treating cancerous conditions with phenylacetic acid and its pharmaceutically acceptable salts and derivatives, including sodium phenylbutyrate (Col. 2, lines 64-67; col. 4, lines 61-67; col. 5, lines 1-15; col. 7, lines 1-4; col. 7, lines 55-57), and as well, cancer prevention (Col. 11, lines 36-47). Samid et al also teach a method of treating the cancer with sodium phenylbutyrate concomitantly or in combination with conventional radiotherapy (Col. 7, lines 47-51). “The compounds of the present invention can be administered intravenously, enterally, parentally, intramuscularly, intranasally, subcutaneously, topically or orally” (Col. 3, lines 42-44). The dosage level of sodium phenylbutyrate administered ranges from 50

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mg/kg/day to 1000 mg/kg/day (Col. 7, lines 14-21). Samid et al also teach that suitable formulations may include: soft gelatin capsules, dragees, pills, tablets, elixirs, suspensions, syrups, inhalations, rectal suppositories, implants, creams, gels, jellies, mucilages, pastes, ointments, infusion solutions, or nasal inhalations or sprays (Col. 24, lines 4-18).

With respect to the reduction in radiation-induced normal tissue damage, the administration of the elected sodium phenylbutyrate to patients undergoing chemotherapy or radiotherapy is expected to have the above mentioned claimed effects, whether recognized by the author or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstance or, in the present case, the same host. Please reference MPEP 2112.

Response to Applicant's Remarks

Applicant alleges that claim 1 has been amended to recite a reduction in radiation-induced normal tissue damage, and further claim 29 requires a cancer-free subject. Firstly, it is noted that Applicant has not amended the claim to exclude cancerous/tumorous cells. Applicant has not defined in the specification what encompasses "normal cells" or "normal tissue." As such, Applicants arguments that the claim excludes tumorous/cancerous cells are not found persuasive. Arguendo the above, if one were to apply Applicant's asserted definition (not defined in the specification) of normal which is non-malignant/cancer free, this definition would remain reading on the prior art. Samid et al. a method of preventing cancer (as admitted by Applicant on page 8 of the response) and therefore administers the agent to noncancerous/cancer-free cells.

Applicant alleges that Shufeng fails to teach the reduction of radiation induced normal tissue damage. This is not found persuasive. As stated in the rejection, with regard to the reduction in radiation-induced normal tissue damage, the administration of the elected compound would necessarily have the effect whether recognized by the author or not. Products of identical chemical composition

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cannot exert mutually exclusive properties when administered under the same circumstance or, in the present case, the same host. Please reference MPEP 2112.

Applicant alleges that the Examiner should consider the non-elected histone hyperacetylating agents of claims 7-10, 12 and 13. The election of species is maintained for the reasons set forth in the election of species mailed on 12/19/2006.

CONCLUSION

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 7am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/

Supervisory Patent Examiner, Art Unit 1628